

II. REMARKS

Upon entry of the present amendment, claims 31 to 37, 39, 40, and 51 to 65 will be pending.

A. Regarding the Amendments

Claims 38, 53, and 57 are cancelled herein without disclaimer, and without prejudice to Applicants' pursuing prosecution of subject matter encompassed within one or more of the claims in an application claiming the benefit of priority of the subject application.

Claim 31 has been amended to clarify that the kit comprises a "microarray comprising" a plurality of uncharacterized antibodies, thus allowing for characterized antibodies also to be present on the microarray with the plurality of uncharacterized antibodies. The amendment is supported, for example, at page 29, lines 7-9, which describes microarrays of uncharacterized antibodies, and page 30, lines 11-14, which discloses that in a further aspect, the microarrays can be composed of previously characterized antibodies.

Claim 37 has been amended to refer specifically to a microarray, and to clarify that the microarray comprises uncharacterized antibodies. The amendment is supported by original claim 31 and, for example, at page 6, lines 8-10; page 29, lines 7-9; and page 30, lines 11-14. The claims depending from claim 37 have been amended such that the language corresponds to amended claim 37. As such, the amendments to the claims do not add new matter.

New claims 60 to 65 have been added. New claims 60, 61, 63, and 64 are supported, for example, at page 15, lines 8-11. New claims 62 and 65 are supported, for example, at page 6, lines 11-13. As such, new claims 60 to 65 do not introduce new matter.

B. Regarding the Information Disclosure Statement

Applicants acknowledge that references cited in the patent application, but not on a Form 1449 or Form 892, have not been considered.

C. Regarding the Drawings

Formal drawings were submitted with Applicants' Amendment mailed July 2, 2003, in U.S. Serial No. 10/035,368, which is a Continuation of the subject application. It is noted that the request for corrected Drawings in Serial No. 10/035,368 was based on the Draftspersons Notice for the subject application. As such, it is respectfully requested that the formal drawings submitted in Serial No. 10/035,368 be used for the subject application, and, accordingly, that the present objection to the drawings be withdrawn.

D. Rejections under 35 U.S.C. § 112

The rejections of claims 31 to 40 and 51 to 59 under 35 U.S.C. § 112, second paragraph, as allegedly vague and indefinite, are respectfully traversed.

It is stated that the term "uncharacterized" in claim 31 (see, also, amended claim 37) is a relative term that renders the claim indefinite because it is not clear whether the uncharacterized antibodies are known or unknown, or are uncharacterized, for example, with respect to the antigen that is bound, or the affinity. Applicants submit, however, that "uncharacterized" is not a relative term, but clearly means "not characterized". As such, it is submitted that the skilled artisan, reading claim 31, clearly would know that "uncharacterized" antibodies are not characterized, for example, with respect to antigen binding and/or affinity. Accordingly, it is respectfully requested that this ground of rejection be removed.

It also is stated that claims 31, 32 and 36 to 38 are indefinite in reciting "instructions" for use because the claims do not set forth any step involved in the method/process and, therefore, it is unclear what method/process is intended to be encompassed. Applicants note that claim 37 no

longer recites to “instructions” and that claim 38 has been cancelled. With respect to claims 31 and 32, Applicants submit that the “instructions” are a physical component of the claimed kits (e.g., paper upon which directions are provided, or that direct the user to a web site that provides directions for using the microarray). As such, while the instructions provide directions for “using” the microarray of a kit, it is submitted that the skilled artisan clearly would know that the instructions are a physical component associated with the kit (e.g., paper which contains information, or directs the user to the information, for using the kit). The Examiner further notes that limitations regarding instructions for utility are not given patentable weight in a kit claim. Applicants do not disagree with the Examiner’s position in this respect, and point out that the “use” recited in the claim is merely descriptive and is not intended as a “limitation”. As discussed above, the “instructions” of the kit are a physical component of the kit and, therefore, it is respectfully requested that this ground of rejection be removed.

Claim 51 is alleged to be vague in reciting “source of” the antibody (see, also, claim 55). Although the Examiner acknowledges that the phrase has a defined meaning, it is stated that it is not clearly defined in the method of the instant application. It is stated, for example, that it is not clear if the term means that the antibody is known to occupy a specific position, or is directed to the origination of the antibody. Applicants first wish to clarify, as discussed above, that the claim is not directed to a “method”, but to compositions (kits). Further, the specification provides an example of a “source of” antibodies, including, for example, a particular hybridoma (page 6, lines 11-13). As such, it is submitted that the skilled artisan clearly would know that the term “source of”, as used in claim 51 (and claim 55), refer, for example, to a particular polyclonal sera or cell line, from which an antibody at a specific discrete location was obtained (see, also, newly added claims 62 and 65, which recite that “the source of the antibodies is a known hybridoma cell line”). Accordingly, it is respectfully requested that this ground of rejection be removed.

For the reasons set forth above, it is submitted that the claims clearly define the subject matter of the invention such that the skilled artisan would know the metes and bounds of the claimed invention. Accordingly, it is respectfully requested that the Examiner reconsider and remove the rejections of the claims under 35 U.S.C. § 112, second paragraph.

E. Prior Art Rejections

The rejection of claims 31, 32, 36 to 58, 53, 54, 57 and 58 under 35 U.S.C. §102(b) as allegedly anticipated by Hirschfeld (U.S. Pat. No. 4,514,508) is respectfully traversed.

It is stated in the Office Action that Hirschfeld describes kits (diagnostic packs) with antibodies immobilized on solid phase surfaces (e.g., microtiter plates), including antibodies against specific antigens (“characterized” antibodies). With respect to “uncharacterized” antibodies, it is stated that the reference describes immobilization of a plurality (e.g., various IgG preparation) of “any” antibody and, therefore, “inherently reads on characterized and uncharacterized antibodies” (Office Action, page 5).

Applicants submit that Hirschfeld does not teach or suggest a “microarray comprising uncharacterized” antibodies because there is no mention of anything other than “characterized” antibodies in the cited reference (see, e.g., column 4, lines 12-14), and because the reference provides no indication of a solid support other than a 96 well plate. The Examiner points, for example, to Example 3, lines 19-24, as supporting the position that Hirschfeld teaches uncharacterized antibodies. However, at the cited passage, Hirschfeld specifically refers to “Various IgG preparations directed against different antigens or haptens....” As such, it would appear that the reference describes “characterized” antibodies because Hirschfeld states that the antibodies are “directed against different antigens or haptens”.

Further, Hirschfeld mentions a solid phase matrix such as a microtiter plate (see, e.g., Abstract, and col. 4, lines 6-11), but does not teach or suggest a microarray. In this respect, Applicants point out that it is well known in the art that a “microarray” comprises an array of

regions having a density of discrete regions of at least about $100/\text{cm}^2$ (see, e.g., WO 95/35505, a copy of which is attached as Exhibit A; see page 12, lines 3-5; Note – WO 95/35505 is incorporated by reference into the subject application at page 15, lines 6-8).

Applicants submit that, absent any mention of uncharacterized antibodies or of microarrays, and absent any reason for preparing a microarray comprising a plurality of uncharacterized antibodies, the Hirschfeld reference would not have placed a microarray comprising a plurality of uncharacterized antibodies, as recited in the claims, in the possession of the public. Accordingly, it is submitted that Hirschfeld does not anticipate the claimed subject matter and, therefore, respectfully requested that the Examiner reconsider and remove the rejection of the claims under 35 U.S.C. §102(b).

The rejection of claims 33 to 35, 39, 40 and 49 under 35 U.S.C. §103(a) as allegedly obvious over Hirschfeld in view of Raag and Whitlow is respectfully traversed.

Hirschfeld is applied as above. It is stated in the Office Action that Hirschfeld does not describe antibody fragments such as single chain or recombinant antibody compositions, but that Raag and Whitlow describe such antibodies, including, for example, single chain recombinant antibody fragments. It is alleged that it would have been obvious to use antibody fragments as described by Raag and Whitlow in the kit and method of Hirschfeld because Raag and Whitlow teach that the smaller antibody fragments allow reduced reaction times such as in ELISA procedures. As discussed above, however, Hirschfeld does not teach or suggest “a microarray comprising a plurality of uncharacterized” antibodies. Similarly, Raag and Whitlow do not describe “a microarray” or “uncharacterized” antibodies and, therefore, do not provide the teaching that is missing in Hirschfeld. As such, it is submitted that the claimed invention would not have been obvious in view of the Hirschfeld reference and the Raag and Whitlow reference, whether considered alone or together. Accordingly, it is respectfully requested that the rejection of claims 33 to 35, 39, 40 and 49 as allegedly obvious over Hirschfeld in view of Raag and Whitlow be removed.

The rejection of claims 51, 52, 55 and 56 under 35 U.S.C. §103(a) as allegedly obvious over Hirschfeld in view of Heller et al. is respectfully traversed.

Hirschfeld is applied as above. It is stated in the Office Action that Hirschfeld does not describe antibody compositions at known spatially addressable locations on an array or in a 96 well microtiter plate, but that Heller et al. describe a microelectronic device designed to carry out molecular biological reactions, including, for example, addressable microlocations positioned on a substrate. It is alleged that it would have been obvious to use a device as described by Heller et al. to position antibody compositions at spatially addressable locations on the array (or microtiter plate) in the kit and method of Hirschfeld for the advantage of performing multiple sample analysis. As discussed above, however, Hirschfeld does not teach or suggest a microarray comprising a plurality of "uncharacterized" antibodies. Similarly, Heller et al. do not describe "uncharacterized" antibodies and, therefore, do not provide the teaching that is missing in Hirschfeld. Further, Heller et al. provide no methods or data for making or using a microelectronic device containing protein arrays such as antibody arrays and, therefore, do not provide an enabling disclosure that would allow for successful combination with the teachings of Hirschfeld. As such, it is submitted that the claimed invention would not have been obvious in view of the Hirschfeld reference and the Heller et al. reference, whether considered alone or together. Accordingly, it is respectfully requested that the rejection of claims 51, 52, 55 and 56 as allegedly obvious over Hirschfeld in view of Heller et al. be removed.

In view of the amendments and the above remarks, it is submitted that the claims are in condition for allowance, and a notice to that effect respectfully is requested. The Examiner is invited to contact Applicants' undersigned representative if there are any questions relating to this application.

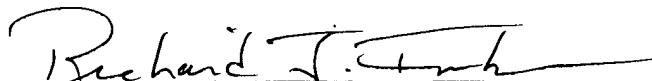
In re Application of
Hoeffler et al.
Application No: 09/245,615
Filed: February 4, 1999
Page 12

PATENT
Attorney Docket No.: INVIT1100-1

If any fee is deemed necessary in connection with the filing of the present Amendment,
the Commissioner is authorized to charge Deposit Account No. 07-1896.

Respectfully submitted,

Date: January 13, 2005


Richard J. Imbra
Registration No. 37,643
Telephone No.: (858) 677-1496
Facsimile No.: (858) 677-1465

DLA PIPER RUDNICK GRAY CARY US LLP
4365 Executive Drive, Suite 1100
San Diego, CA 92121-2133
USPTO CUSTOMER NO. 28231

Enclosure: Exhibit A